REMARKS/ARGUMENTS

In response to the Final Office Action mailed May 15, 2009, Applicants propose to amend their application and request reconsideration in view of the proposed amendments and the following remarks. In this amendment, Claim 1 is proposed to be amended, no claims have been added, or cancelled without prejudice, and claims 9 and 10 have been previously withdrawn so that Claims 1, 4, 5, and 9-10 are currently pending. No new matter has been introduced.

Claims 1 and 4 were rejected as being unpatentable over EP0041795A2 to Sehgal in view of U.S. Patent No. 5,891,845 to Myers. Claim 5 was rejected as being unpatentable over Sehgal in view of Myers and further in view of U.S. Patent No. 7,060,709 to Cooperstone et al. These rejections are respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

> "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested

> by the prior art. In *re Royka*, 490F.2d 981, 180 USPQ 580 (CCPA 1074). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In *re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In *re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)."

Sehgal discloses an injectable composition of rapamycin. The composition provides for 1 to 20 milligrams of rapamycin per milliliter of the composition and a nonionic surfactant. Various concentrations are illustrated. The injectable rapamycin composition comprises rapamycin, a nonionic surfactant and water. Upon removal of the solvent, the rapamycin remains in solution in the nonionic surfactant. Dilution of the above solutions containing rapamycin, solvent and nonionic surfactant or rapamycin and nonionic surfactant with water.

Myers discloses drug delivery systems utilizing liquid crystal structures. Myers discloses the use of vitamin E EPGS with cyclosporine.

Cooperstone discloses the use of a rapamycin 42-ester with 3-hydroxy-2-(hydroxymethy6l)-2-methylpropionic and n the treatment of hepatic fibrosis and hepatic cirrhosis.

None of the references, whether taken alone or in combination disclose or suggest the invention of independent claim 1. Sehgal discloses an injectable composition of rapamycin that comprises no vitamin E in the final product. In addition, it is diluted with water for injection. There is no stable solution containing water. Myers discloses vitamin E TPGS/drug compositions. It is respectfully submitted that vitamin E TPGS has been known for at least 20 years as a water soluble version of vitamin E and as an excipient for pharmaceutical applications. It is specifically stated on page 4, lines 20 to 25 that it is an injectable aqueous formulation and not a stable one> "Dilution of the above solutions containing rapamycin, solvent nonionic surfactant or rapamycin …

suitable for injection. This dilution is preferably made shortly before administration, e.g. within four hours before injection…" This is an admission that it is not a stable solution as is now very clearly set forth in amended claim 1. Myers teaches a solid solution of vitamin E TPGS and a pharmaceutical agent. This is not a liquid solution utilizing water, but rather a binary system of equal amounts of vitamin E and agent. Once again, no stable solutions and no reasons to combine since Sehgal dilutes with water only for IV use. A solid solution is blended on the molecular level and there is no use of water or co-solvents. In the present invention we utilize water and not a solid or molecular solution. The present invention also claims an aqueous solution, none of the other references discloses or suggests an aqueous solution. Copperstone adds nothing with respect to the rejection of claim 1. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicant would be grateful for the opportunity to conduct a telephonic or in-person interview of the Examiner believes it would be helpful in disposing of the present case.

A favorable action on the merits is earnestly solicited.

Respectfully submitted,

/Carl J. Evens/

By:_____
Carl J. Evens
Reg. No. 33,874

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2518
Dated: July 14, 2009